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09/858,366	05/16/2001	Richard A. Brauckman	TGXX-1005US	3214

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KNOBLE & YOSHIDA, LLC
Eight Penn Center
Suite 1350
1628 John F. Kennedy Blvd.
Philadelphia, PA 19103

EXAMINER
RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
3751	

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/858,366	Applicant(s) BRAUCKMAN ET AL.	
	Examiner Anu Ramana	Art Unit 3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☒ Claim(s) 31-36 is/are objected to. Misnumbering

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed feature "structure for attaching the catheter attachment to a catheter" of claims 21-30 must be shown or the feature canceled from the claim. No new matter should be entered.

The drawings are also objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference elements mentioned in the description: "17" (page 6, line 15) and "39" (page 8, line 32). Further, element "61" is not shown clearly in Figure 7. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of minor typographical errors, for e.g. "for the a," (page 8, line 22). The text must be checked for minor errors with appropriate correction.

On page 12, lines 14-18 appear to be inconsistent with the operation of the device described in the following paragraph on the same page. Appropriate correction is required.

Claim Objections

Claims 31-36 are misnumbered since all claims must be consecutively numbered (see 37 CFR 1.126).

Misnumbered claims 31-36 have been renumbered 30-35. The text of claims dependent thereon must be amended to match the corrected numbers.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 12, 19 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 (line 4) and 19 (line 4) recite the limitation "to which the radioactive source is bonded". There is insufficient antecedent basis for this limitation in the claim.

Claim 12 is vague and indefinite because it omits essential structural cooperative relationships of elements, i.e, catheter body and carrier. A suggested cure is "wherein the radioactive source is housed in the distal end of a carrier located in the catheter body."

Claim 32 is vague and indefinite because the claimed limitation "the structure" lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939) in view of Alt (US 5,871,437).

Duke et al. disclose a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter (Figure 1, Figure 9, col. 2, lines 49-54, col. 3, lines 58-68 and col. 4, lines 1-8 and lines 34-36) wherein the radioactive means can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12. Duke et al. also disclose that catheter 10 has stiffening elements "sufficient strength and flexibility" to navigate vasculature without crimping (col. 4, lines 9-16). Duke et al. also disclose that the radioactive means 14 provides from 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (col. 5, line 68 and col. 4, lines 1-5).

Duke et al. do not disclose that the radioactive source 14 is bonded to the surface of body 12.

Alt teaches coating the surface of a stent with a polymer carrier containing a suitable amount of radioactive material or "a radioactive source" to provide a desired level of radioactivity wherein to ensure tight adherence of the carrier material to the surface of the metallic or non-metallic stent, the carrier material is applied in successive thin layers (col. 6, lines 52-66, col. 7, lines 24-27, and col. 8, lines 30-36).

It is well known that bonding of one material to the surface of another material requires proper bonding or adherence by ensuring sufficient bond strength to prevent subsequent separation of the materials. Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a coating containing radioactive material or a radioactive source onto body 12 in the radioactive segment 30 of the catheter of Duke et al. wherein the radioactive source is bonded to the distal section 20 with sufficient bond strength for proper adherence as taught by Alt. Further, it would have been obvious to have provided a suitable amount of radioactive material in the coating to obtain the claimed level of radioactivity of 0.5 microcuries to about 300 curies per centimeter length, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939) in view of Alt (US 5,871,437), as applied to claim 1, further in view of Hess (US 5,302,168).

Duke et al. do not disclose that catheter 10 is a balloon catheter wherein the radioactive source 14 is located on the expandable portion of the balloon. A balloon catheter is a well known type of catheter.

Regarding claim 2, Hess teaches device 10 for radiation treatment including a balloon 36 with radioactive elements or source 38 attached thereto (col. 3, lines 41-45, Figure 2 and Figure 4) wherein the balloon 36 is expanded in the vicinity of the lesion or treatment site and the radioactive source 38 is forced into contact with the treatment site.

Regarding claim 5, Hess teaches an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site such that a window cut-out 32 in radiation source 30 is opened to expose the treament site to a radiation dose (col. 3, lines 26-40).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath as taught by Hess in the catheter 10 of Duke et al. for radiation containment or to have substituted catheter 10 of Duke et al. with a balloon catheter having a balloon 36 with a radiation source 38 attached thereto as taught by Hess in the device 10 of Duke et. al so for forced contact of the radiation source with the treatment site.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939) in view of Alt (US 5,871,437), as applied to claim 1, further in view of Weinberger et al. (US 6,217,503).

Duke et al. do not disclose a balloon catheter having a radiation producing coating.

Weinberger et al. teaches a balloon catheter having a radiation producing coating on an exterior surface (col. 4, lines 56-57) or on an internal surface (col. 12, lines 50-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radiation producing coating on an internal or external surface as taught by Weinberger et al as the radioactive source 14 in the catheter 10 of Duke et al. wherein the coating is properly adhered to the surface of catheter 10 as taught by Alt.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939) in view of Alt (US 5,871,437), as applied to claim 1, further in view of Carden, Jr. (US 5,405,309).

Duke et al. do not disclose carrier-free palladium 103 as the radiation source.

Carden, Jr. teaches preparation of carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-41, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free Pd-103 as the radiation source in the catheter 10 of Duke et al. as modified by Alt for enhanced safety.

Claims 7, 8, 12, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939), as applied to claim 1, in view of Liprie (US 5,282,781).

Duke et al. disclose that the radioactive means is a plurality of cylindrical pellets 14 in having a sufficiently small diameter to fit within the distal end or radioactive segment 30 of catheter body 12 (Figure 9 and col. 5, lines 18-24).

Duke et al. do not specifically disclose that the catheter body 12 provides access to the cavity housing the radioactive source.

Liprie teaches a wire assembly 10 having a hollow tube ("catheter") with a radioactive source 25 housed in a cavity in the distal end of the tube 10 wherein a plug 27 is utilized for placement and containment of radioactive source 25 within the cavity and a backbone wire or "guidewire 17" to enhance the flexibility of the tube 10 (col. 5, lines 63-68, col. 6, lines 1-15 and lines 41-68, Figure 1, col. 10, lines 21, 25-26, and 48-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the catheter body 12 of Duke et al. wherein a plug 27 is provided for placement and containment of radioactive source 25 as taught by Liprie. Although, Liprie does not specifically teach that plug 27 is removable after placement, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a removable plug 27 since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Further, it would have been obvious to have provided a suitable amount of radioactive material in the housing to obtain a radioactivity level of 0.5 microcuries to about 300 curies per centimeter length of the radioactive segment 30, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding claims 12 and 15, Liprie teaches that wire assembly or "carrier" 10 has an overall diameter to permit movement thereof within an outer catheter (col. 5, lines 54-62).

Claims 9, 10, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939) in view of Liprie (US 5,282,781), as applied to claim 7, further in view of Leavitt et al. (US 6,352,682B1).

Duke et al. do not disclose that the radioactive source 14 is immobilized in a polymeric material that is selected from the group of elastomers, gels etc.

Leavitt et al. teach a polymer depot or radioactive source wherein a radioactive material is immobilized in a polymeric material that can be in the form of a gel (col. 1, lines 49-51, col. 2, lines 39-43, col. 3, lines 44-48 and col. 4, line 52) as a source of radiation.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the catheter body 12 of Duke et al. as modified by Liprie wherein the radioactive source is immbolized in a polymeric material in the form of a gel as a source of radiation as taught by Leavitt et al.

Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939)) in view of Liprie (US 5,282,781), as applied to claim 7, further in view of Hess (US 5,302,168).

Duke et al. do not disclose a retractable sheath. It is well known that radiation sources must be handled carefully to prevent radiation exposure (also see Liprie, col. 7, lines 58-68).

Hess teaches device 10 for radiation treatment with a distal radioactive source 38 thereto (col. 3, lines 41-45, Figure 2 and Figure 4) wherein a balloon 36 is expanded in the vicinity of the lesion or treatment site and the radioactive source 38 is forced into contact with the treatment site. Further, Hess teaches an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site such that a window cut-out 32 in radiation source 30 is opened to expose the treament site to a radiation dose (col. 3, lines 26-40).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath in the catheter 10 of Duke et al. as modified by Liprie for radiation containment or shielding as taught by Hess.

Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke et al. (US 5,199,939) in view of Liprie (US 5,282,781), as applied to claim 7, further in view of Carden, Jr. (US 5,405,309).

See discussion for claim 6.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the catheter body 12 of Duke et al. wherein the radioactive source is carrier-free palladium-103 as taught by Carden, Jr. for enhanced safety.

Claims 21, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,302,168) in view of Duke et al. (US 5,199,939) further in view of Gupta (US 5,718,684).

Hess teaches device 10 for radiation treatment including a catheter shaft 40, a balloon (expandable portion) or substrate 36 with radioactive elements or source 38 attached thereto wherein the substrate 36 is expanded in the vicinity of the lesion or treatment site and the radioactive source 38 is forced into contact with the treatment site (col. 3, lines 41-45, Figure 2 and Figure 4).

Hess does not disclose that the substrate or balloon is provided with structure for attachment to a catheter. Further, Hess does not disclose that the radioactive source 38 provides radiation in an amount from about 0.5 microcuries to about 300 curies per centimeter length of the radioactive segment.

Duke et al. teach a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter (Figure 1, Figure 9, col. 2, lines 49-54, col. 3, lines 58-68 and col. 4, lines 1-8 and lines 34-36) wherein the radioactive means can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12. Duke et al. also disclose that the radioactive means 14 provides from 10 microcuries to about 100 curies per

centimeter length of the radioactive segment 30 (col. 5, line 68 and col. 4, lines 1-5). Duke et al. further disclose that the radioactive means can be in the form of radioactive pellets 14 housed inside tube or substrate 12 (col.5, lines 19-24 and Figure 2).

Gupta teaches a balloon or substrate 30 that is mounted or attached on and around the shaft of a catheter 20 at its distal portion 27 by bonding (Figure 1, Figure 3, Col. 3, lines 24-26) for use in vascular cavities of a body for treatment of stenosis (col. 2, lines 32-33 and col. 4, lines 30-34) wherein balloon 30 is mounted or secured by bonding to the shaft of a catheter 25 (col. 3, lines 30-32). Further, Gupta teaches multiple chambers a plurality of lobes or chambers 29e, 29f, 29g and 29h that are in communication with a flow passage 22 (col. 3, lines 40-42).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have mounted an attachment 30 on the distal end of catheter shaft 40 of Hess, as taught by Gupta, with a radiation source 38 attached thereto wherein source 38 is bonded outside or inside catheter shaft 40 providing radiation in an amount from about 0.5 microcuries to about 300 curies per centimeter length of the radioactive portion of the catheter shaft 40 as taught by Duke et al. since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Further, although Gupta does not disclose that attachment 30 is removably attached to the distal portion 27 of catheter shaft 40, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided conventional means for removable attachment such as threads, interference or snap-fit, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Regarding claim 26, Hess discloses an alternate embodiment 60 of device 10 wherein the radioactive dose means 64 is housed in the shaft portion or substrate of device 60.

Claims 22-24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,302,168) in view of Duke et al. (US 5,199,939) further in view of Gupta (US 5,718,684), as applied to claim 21, further in view of Krasnicki et al. (US 4,676,229).

Hess does not disclose that the radiation source or radioactive elements 38 are attached or bonded to the surface of substrate 36 with sufficient bond strength.

Krasnicki et al. teach attachment of two materials, filament 35, and a substrate 31 by using an adhesive having sufficient bond strength (col. 3, lines 49-53 and Figure 2).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached radiation source or elements 38 to the surface (either inside or outside) of substrate 36 of the Hess device as modified by the teachings of Duke et al. and Gupta utilizing an adhesive with sufficient bond strength as taught by Krasnicki et al. for the purpose of securing elements 38 to substrate 36.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,302,168) in view of Duke et al. (US 5,199,939) further in view of Gupta (US 5,718,684), as applied to claim 26, further in view of Leavitt et al. (US 6,352,682B1).

Hess does not disclose that the radioactive material is immobilized in a polymeric material.

Leavitt et al. teach a polymer depot or radioactive source wherein a radioactive material is immobilized in a polymeric material that can be in the form of a gel (col. 1, lines 49-51, col. 2, lines 39-43, col. 3, lines 44-48 and col. 4, line 52) as a source of radiation.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source 14 immobilized in a polymeric material that can be in the form of a gel as taught by Leavitt et al. in the device of Hess as modified by the teachings of Duke et al. and Gupta as a source of radiation.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,302,168) in view of Duke et al. (US 5,199,939) further in view of Gupta (US 5,718,684), as applied to claim 21, further in view of Carden, Jr. (US 5,405,309).

Hess does not disclose the use of Pd-103 as a radiation source.

Carden, Jr. teaches preparation of carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-41, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free palladium-103 as taught by Carden, Jr. in the device of Hess as modified by the teachings of Duke et al. and Carden, Jr. for enhanced safety.

Claim 31, 33, 34 and 35 *are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,302,168) in view of Gupta (US 5,718,684).*

Hess teaches device 10 for radiation treatment including a catheter shaft 40, a balloon or expandable housing 36 with radioactive elements or radiation source 38 attached thereto (col. 3, lines 41-45, Figure 2 and Figure 4) wherein the substrate 36 is expanded in the vicinity of the lesion or treatment site and the radiation source 38 is forced into contact with the treatment site.

Hess does not disclose that device 10 is provided with a mount for attachment to a catheter. Further, Hess does not disclose that expandable housing 36 has a plurality of chambers.

Gupta teaches a balloon or expandable housing 30 that is mounted or attached on and around the shaft of a catheter 25 at its distal portion 27 by bonding (Figure 1, Figure 3, Col. 3, lines 24-26) for use in vascular cavities of a body for treatment of stenosis (col. 2, lines 32-33 and col. 4, lines 30-34) wherein balloon 30 is mounted or secured by bonding to the shaft of a catheter (col. 3, lines 30-32). Further, Gupta teaches multiple chambers a plurality of lobes or chambers 29e, 29f, 29g and 29h that are in communication with a flow passage 22 (col. 3, lines 40-42).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have mounted a balloon 30 on the distal end of catheter shaft 40 of Hess, as taught by Gupta, with a radiation source 38 attached thereto for treatment. Further, although Gupta does not disclose that attachment 30 is removably attached to the distal portion 27 of catheter shaft 40, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided conventional means for removable attachment such as threads, interference or snap-fit, since it has been held that constructing a formerly integral structure (bonding) in various elements (separable mounting) involves only routine skill in the art.

Regarding claim 34, Hess discloses a sheath 50 to provide shielding for the radioactive does means 54 (Figure 5, col. 4, lines 15-23). Hess does not disclose a radiation stable outer coating.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a radiation stable outer coating instead of a sheath since the

examiner takes Official Notice of the equivalence of a sheath and a coating for their use in the art for the purpose of covering a surface and the selection of any of these known equivalents for the purpose of covering device 10 of Hess would be within the level of ordinary skill in the art.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,302,168) in view of Gupta (US 5,718,684) further in view of Fagan et al. (US 5,645,529).

Neither Hess nor Gupta disclose or teach that the expandable balloon of the Hess device as modified by the teachings of Gupta does not occlude a vessel or lumen in when placed and expanded in the vessel or lumen.

It is well known that multi-lobed balloon catheters are utilized to prevent occlusion of the lumen in which they are inserted. For example, Fagan et al. teach a plurality of lobes or chambers 61 and a shaft opening 63 wherein some of the lumens 62 may be open and can be used to perfuse blood therethrough to minimize trauma that would be otherwise caused by the balloon fully occluding the artery when the balloon is inflated (Figures 6a-6d , Figure 7, col. 6, lines 4-9 and lines 51-65).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized any unused lumens in the device Hess as modified by the teachings of Gupta to prevent occlusion of the vessel in which the device is inserted.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Saab (US 5,624,392):

Figure 1, Figure 7, col. 3, lines 53-65, col. 7, lines 64-66, and col. 9, lines 8-25.

McGarth et al. (US 6,036,631):

Col. 3, lines 56-62, col. 4, lines 11-13, and col. 5, lines 31-44

Koelmel et al. (US 4,546,152) :

Col. 1 and col. 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached on 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR
August 25, 2002

8/25/02

GREGORY HUSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700